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## This week in the BMJ

### Treat low back pain with acupuncture



MARK DE FRIEVE/WEELCONE PHOTO LIBRARY

Acupuncture is more effective than standard physical therapy in alleviating low back pain in terms of pain scores, functional status, and disability. Hsieh and colleagues (p 696) randomised 129 patients with chronic low back pain to one month's (six sessions) treatment with acupuncture or routine physical therapy. Acupuncture produced significantly greater improvement in outcome measures both immediately after treatment and at the six month follow-up.

### Education can improve GPs' detection of dementia



BRIPHASSET/SPR

Decision support software and practice based workshops are effective educational approaches in improving rates of detecting dementia in primary care. Downs and colleagues (p 692) randomised 35 UK general practices to one of three

educational interventions (an electronic tutorial on CD Rom, decision support software built into the electronic medical record, or practice based workshops) or control. The latter two interventions significantly improved rates of detection compared with control practices, but there were no significant differences by study arm in the management of dementia.

### Breast cancer screening yields 10% over-diagnosis



ALEXPHAN/REX

Mammographic screening of women aged 55 years or older leads to a 10% over-diagnosis of breast cancer (detection of cases that would otherwise never have come to clinical attention). Zackrisson and colleagues (p 689) undertook a follow-up study of the participants from a Swedish trial that had randomised more than 42 000 women aged 45-69 to mammographic screening or not (control). Fifteen years after the end of that trial, over-diagnosis was 10% in the women randomised to screening at age 55-69 compared with the unscreened controls.

### Should all children be immunised against hepatitis A?

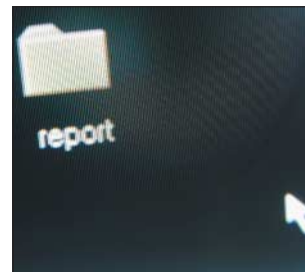
Given the recent US recommendation for vaccination of all children against hepatitis A, Temte (p 715) examines the evidence on hepatitis A epidemiology, childhood vaccinations, and



VOISINPHAN/REX

issues relating to vaccine policy. The new recommendation is based on strong epidemiological evidence of its effectiveness but is compromised by the reduced prevalence of the virus thanks to the success of targeted vaccination. Temte warns that adding two more injections to an already crowded vaccination schedule may reduce compliance and increase the already high costs but concludes that the recommendation is probably justified.

### Cost effectiveness studies show publication bias



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Most published cost effectiveness analyses report favourable cost effectiveness ratios below the thresholds set for good value. Bell and colleagues (p 699) carried out a systematic review of 494 studies measuring health effects in quality adjusted life years (QALYs) and found that two thirds of published cost effectiveness ratios were below the threshold of \$50 000/QALY and only 21% were above \$100 000/QALY. Published cost effectiveness analyses are of limited use in identifying health interventions that do not meet popular standards of "cost effectiveness," say the authors.

## Cone biopsy shortens the cervix and is associated with preterm birth in later pregnancies

**Research question** Does vaginal ultrasonography help predict preterm birth among women who have been treated for cervical intraepithelial neoplasia?

**Answer** Possibly. Vaginal ultrasonography may help predict preterm birth among women who have had loop electrosurgical excision.

**Why did the authors do the study?** Some evidence exists that treatments for cervical intraepithelial neoplasia, such as cone biopsy, are associated with preterm birth. If so, a shortened cervix could be to blame. These authors wanted to find out if measuring the cervix in mid to late pregnancy could help predict preterm birth among women who have had cervical procedures.

**What did they do?** They compared three groups of pregnant women: 132 who had had loop electrosurgical excision, cold knife conisation, or cryotherapy for cervical intraepithelial neoplasia, 63 who had had a spontaneous preterm birth, and 81 who had had neither. The authors measured the women's cervixes by using vaginal ultrasonography between 24 and 30 weeks of pregnancy and followed them up until the birth. They looked for differences in cervical length and incidence of preterm birth between the three groups and then did a multiple logistical regression analysis to find out which cervical procedures were independently associated with preterm birth. Finally, they estimated the predictive value of a short cervix for preterm birth among women who had had loop electrosurgical excision.

**What did they find?** Women who had had any cervical procedure had a shorter cervix mid-pregnancy than low risk controls (mean length 3.54 cm, 3.69 cm, 3.75 cm among women with loop excisions, cold knife conisation, and cryotherapy compared with 4.21 cm among controls;  $P < 0.05$  for all procedures). Women with a previous preterm birth also had a shorter cervix (3.78 cm).

The two types of cone biopsy, but not cryotherapy, were independently associated with preterm birth (odds ratio 3.45 (95% CI 1.28 to 10) for loop excision and 2.63 (1.28 to 5.56) for cold knife conisation). Among women with a previous loop electrosurgical excision, a cervix less than 3 cm on vaginal ultrasonography predicted preterm birth with a positive predictive value of 53.8% (7/13) and a negative predictive value of 95.2% (59/62). The authors were unable to estimate the predictive value of vaginal ultrasonography for women who had had cold knife conisation because of the small size of their sample.

**What does it mean?** These data add to growing evidence of a link between cone biopsy and preterm birth and are reassuring for women who have had cryotherapy. The strongest findings were for women who had had loop electrosurgical excision, whose risk was three times higher than that of controls. Measuring the cervix of these women in pregnancy may be useful, if only because women with a cervix over 3 cm long seem unlikely to deliver early. Note, however, that the authors had no data on social class and were unable to account for the effects of this important confounder.

Crane JMG, et al. Transvaginal ultrasonography in the prediction of preterm birth after treatment for cervical intraepithelial neoplasia. *Obstet Gynecol* 2006;107:37-44

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## Editor's choice

### Count the harms

Hippocrates may not have foreseen the complexities of modern medicine, but 24 centuries ago he (or whoever wrote the Hippocratic Oath) set down a fundamental rule for all clinicians and researchers—"first do no harm." This rule has special resonance this week as we explore over-diagnosis in breast cancer screening, and the evolving clinical trial nightmare at Northwick Park.

Three weeks ago an editorial in the *BMJ* concluded that despite limitations, breast cancer screening does save lives (*BMJ* 2006;332:499-500). But in the same issue of the journal we published an analysis by Karsten Juhl Jørgensen and Peter Gøtzsche of the letters inviting women for screening (*BMJ* 2006;332:538-541). None of the letters mentioned the major harms of screening, and the authors concluded that organisers of screening programmes have a serious conflict of interest in wanting high uptake, which compromises their ability to provide balanced information about benefits and harms. That same week we also published "online first" Sophia Zackrisson and colleagues' 15 year follow-up from the Malmö trial of screening for breast cancer, which concluded that 10% of cancers detected by screening in women aged 55-69 are over-diagnosed.

This week we pull these strands together, along with letters selected from among the rapid responses to all three pieces (p 727). The total picture is far from reassuring. As Zackrisson et al explain (p 689), their 10% figure is a conservative estimate, since some of the women in the control group also had mammography. In a letter, Gilbert Welch and colleagues suggest that the more relevant figure is 24% since, based on the Malmö data, this is the chance that a screen detected cancer represents over-diagnosis (p 727). Their higher figure is more in line with Gøtzsche's estimate of 30% (p 727). Whatever the figure, or the reasons for it (pp 678, 691 and 727), there seems little doubt among our contributors that over-diagnosis is real and substantial. As Michael Baum relates, his unaddressed concerns about the UK's screening programme, which he helped to set up, led him to resign from the programme committee (p 728). He and Hazel Thornton (p 728) endorse Gøtzsche's concerns about conflicts of interest and the "fobbing off" of women with unbalanced, insufficient information.

Lack of proper information may prove to be at the heart of events that have left six young men seriously ill in hospital after the "first in man" trial of the monoclonal antibody TGN1412 (p 683). Michael Goodyear asks what lessons can be learned from this catastrophe (p 677), and Kate Mandeville describes her own experiences as a clinical trial volunteer (p 735). Questions are mounting about the trial, and they need answering. An inquiry by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) will not be enough, since this body may itself be implicated in mistakes that were made. There must be a full public inquiry if we are to prevent something like this happening again.

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